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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,394	04/19/2004	John K. Jackson	UBC.P-033	5855
21121	7590	02/28/2006	EXAMINER	
OPPEDAHL AND LARSON LLP			VIVLEMORE, TRACY ANN	
P O BOX 5068			ART UNIT	
DILLON, CO 80435-5068			PAPER NUMBER	
			1635	
DATE MAILED: 02/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/828,394	Applicant(s) JACKSON ET AL.	
	Examiner Tracy Vivlemore	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

#### ***Response to arguments: Claim Rejections - 35 USC § 112***

Applicant's submission of the declaration originally submitted in application 09/967,726, describing human administration of antisense oligonucleotides directed to clusterin with a subsequent reduction of clusterin, is sufficient to overcome the rejection for scope of enablement.

Claims 1 and 6 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In regard to oligonucleotide inhibitors of clusterin for species other than humans applicant states that the sequence for clusterin from other species is known and that applicant plainly recognized that the claimed invention was not limited to humans. It is recognized that oligonucleotide inhibitors can be routinely derived for any gene where the sequence is known and applicant is correct that satisfaction of the written description requirement does not require disclosure of what is known in the art, however the scope of the instant claims is directed to inhibition of clusterin in all species and thus encompasses things that are not known in the art. Without a description in the specification or the art of either gene sequences of a number of species sufficient to

represent the claimed scope or a description of essential motifs and/or domains common throughout the known sequences that would allow the skilled artisan to recognize what inhibitors would have the function of inhibiting clusterin in all species, the written description requirement has not been met.

***Response to arguments: Double Patenting***

Claims 1-3 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,900,187.

Claims 1-3 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-39 and 42 of copending Application No. 09/967,726.

The examiner acknowledges applicant's willingness to file a terminal disclaimer if required after indication of allowable subject matter. Until such time, maintaining the rejections is proper.

Claims 1, 2, 6 and 7 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21 and 29 of copending Application No. 10/646,436.

Applicant states this rejection is inappropriate with regard to claims 6 and 7 because these claims require reduction of angiogenesis, which is not mentioned in the '436 application. This argument is not persuasive because claim 29 of the '436 application recites specific cancers such as breast, bladder and lung that can be treated

by the claimed method. These cancers are recited in the instant specification at page 4 as examples of cancerous angiogenesis-related diseases, thus the methods claimed in the '436 application are species that would anticipate of the instant generic methods and the claimed result of reduction of angiogenesis would occur, absent evidence to the contrary.

***Response to arguments: Claim Rejections - 35 USC § 102***

Claims 1, 2, 6 and 7 remain rejected under 35 U.S.C. 102(b) as anticipated by Monia et al. for the reasons set forth in the office action mailed 10/3/05.

Claims 1-3 and 6-8 remain rejected under 35 U.S.C. 102(b) as anticipated by Gleave et al. (WO 00/49937) for the reasons set forth in the office action mailed 10/3/05.

Claims 1-3 and 6-8 remain rejected under 35 U.S.C. 102(e) as anticipated by Gleave et al. (US 6,900,187) for the reasons set forth in the office action mailed 10/3/05.

Claims 1-3 and 6-8 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gleave et al. (US 2003/0158130) for the reasons set forth in the office action mailed 10/3/05.

Applicant has traversed the rejection over Monia et al. by stating the examiner has not identified where in Monia et al. there is a disclosure of reducing angiogenesis. It is correct that Monia et al. is silent with regard to reduction of angiogenesis, but this is not required by claims 1 and 2, simply administration of an oligonucleotide that reduces clusterin to an individual suffering from a cancerous angiogenesis related disease.

Monia et al. disclose at column 3, lines 40-46 a method of treating an animal having a disease associated with expression of clusterin using an antisense oligonucleotide. At column 2, lines 65-66 Monia et al. disclose that gliomas are one disease state associated with clusterin expression. Gliomas are cancerous angiogenesis-related diseases as evidenced by Kunkel et al. (Cancer Research 2001), who teach that gliomas exhibit angiogenesis.

Applicant has traversed the rejection over each of the Gleave et al. references by stating that none of these references disclose anything about angiogenesis or angiogenesis-related cancers. This argument is not persuasive because both the WO document and the '187 patent claim methods of treating individuals having prostate cancer. The published '130 application claims methods of treating individual having cancers that include prostate cancer, bladder cancer, ovarian cancer and lung cancer. Each of these cancers is disclosed in the instant application at page 4 as examples of cancerous angiogenesis-related diseases.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

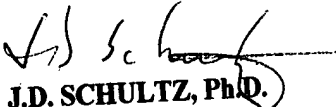
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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
February 14, 2006



**J.D. SCHULTZ, Ph.D.**  
**PATENT EXAMINER**